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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/769,245	01/26/2001	Jeffrey Ray Stout	BO 44277	5103

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EXAMINER
CHOI, FRANK I

ART UNIT	PAPER NUMBER
1616	

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7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/769,245	Applicant(s) STOUT ET AL.	
	Examiner Frank I Choi	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sh et with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 April 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Objections

Claim 1, 9 is objected to because of the following informalities:

Except for abbreviations a claim should contain only a single period at the end of the sentence. Examiner suggests removing "a.", "b." and "c." or using parentheses in claim 1.

Claim 9 should recite "group consisting of".

Claim 12 should recite "organic creatine"

Claim 14 should recite "grams of" instead of "gram" or "g" and should recite "blood buffer" and "further comprising . . . carbohydrates".

Claim 23 should recite "blood buffer" and "biocarbonate" should be "bicarbonate"

Claims 21 and 22 should begin with "The" not "A".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. In the present

instance, claim 3 recites the broad recitation "1:10 to about 1:1", and the claim also recites "preferably about 1:6 to about 1:4" which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 1–5, 10,11,13, 14, 16-19, 21, 22, 25 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Simone (US Pat. 5,397,786).

Simone expressly discloses a composition and method of administering the same to athletes comprising carbohydrates, carbohydrates, including dlucoe polymers, maltodextrin and fructose, potassium bicarbonate, sodium bicarbonate, potassium phosphate, sodium phosphate, calcium carbonate, magnesium carbonate, aspartic acid or magnesium aspartate, L-arginine, glutamate, vitamins, L-canitine, creatine, choline chloride, leucine, isoleucine, selenium, betaine chloride, methionine and octacosanol (Columns 4-12, Claims 14, 15) falling within the scope of applicant's claims.

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products and uses that contain the same exact ingredients/components as that of the claimed invention. See In re May, 197 USPQ 601, 607 (CCPA 1978). See also Ex parte Novitski, 26 USPQ2d 1389, 1390-91 (Bd Pat. App. & Inter. 1993).

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simone (US Pat 5,397,786) in view of Weinstein et al. (U.S. Pat. 6,013,290), WO 96/04240, Fang (U.S. Pat. 5, 886,040), Webster's Dictionary (10th Ed.), Odian et al. (Schaum's Outline), Hultman et al. (U.S. Pat. 5,767,159) and St. Cyr et al. (U.S. Pat. 6,159,942).

Simone teaches a composition and method for rehydrating athletes, containing carbohydrates, potassium bicarbonate, sodium bicarbonate, potassium phosphate, sodium phosphate, calcium carbonate, magnesium carbonate and creatine (Columns 4-12, Claims 14, 15).

Weinstein et al. teaches that for person's who are exercising and replenishing lost water, sodium is necessary to prevent hyponatremia and allow optimal restoration of lost fluid (Column 4, lines 20-28). Is taught that carbohydrates are useful for recovery of muscle glycogen after exercising (Column 4, lines 30-68). It is taught that sodium bicarbonate, sodium citrate and potassium citrate are alkaline buffers improve performance in athletes utilizing the anaerobic energy system by counteracting the increasing acidity of blood caused by exercise and which acidity contributes to fatigue (Column 5, lines 50-58). It is taught that creatine supplementation for allows high rates of ATP resynthesis (Column 6, lines 7-14). It is taught that phosphates and pyruvates have or may have positive effects on exercise (Column 6, lines 20-24).

WO 96/04240 teaches that mono-, bi- or tri-carboxylic acid salts of creatine, including citrate, maleate, fumarate, tartrate or malate, exhibit increased hydrosolubility and increased bioavailability over creatine, with the citrate, maleate and tartrate salts exhibiting a water solubility of 10 g/100 ml, 19 g/100 ml and 8.5 g/100 ml, respectively (Pgs. 1-3).

Fang teaches that creatine pyruvate is more water soluble than creatine and enables the optimal biofunctionality of both creatine and pyruvate in enhancing energy and metabolic rates (Column 8, lines 19-35).

Webster's Dictionary (10^{th} Ed.) defines "precursor" as a substance from which another substance is formed (Pg. 917).

Odian et al. teaches that in the Kreb's cycle, that pyruvate is used to form citrate fumarate and malate, that citrate is used to form fumarate and malate , and that malate is used to form pyruvate (Pgs. 450, 452).

Hultman et al. teaches that creatine phosphate is the substrate in muscular tissue which gives the fastest resynthesis of ATP and that formulations containing creatine include effervescent powders which may be dissolved in water (Column 1, lines 20-35, Column 2, lines 23-27).

St. Cyr et al. teaches that energy buildup in muscle cells is through oxidative phosphorylation which replenishes ATP by breakdown of circulating fatty acids, glucose and intramuscular glycogen and triglcerides and anerobic phosphorylation which provides ATP from creatine phosphate, glucose and intramuscular glycogen via kinase reactions (Column 1, lines 29-43). It is taught that irrespective of the substrates used for the generation of ATP, ATP cannot be synthesized unless that precursors of the ATP molecule itself are available (Column 1,

lines 60-64). It is taught that pentoses, such as ribose, allow athletes to exercise longer with greater energy and that combination with creatine, pyruvate, electrolytes and/or carbohydrates enhance the pentose benefit (Column 3, lines 10-57).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose a composition or method of using the same, comprising a creatine salt, a phosphorous supplement which provides at least 75% of the recommended daily dose value per serving and a blood buffer. However, the prior art amply suggests the same as it is known in the art to prepare nutritional supplements containing creatine, phosphorus and blood buffers for increasing energy and increasing anaerobic work capacity. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the combination of creatine, phosphorus, sodium, blood buffers, organic salts of creatine, Krebs cycle intermediates and precursors thereof, carbohydrates, pentoses would be effective increasing tissue cell energy and anaerobic work capacity and that after the initial adminstration that the increased anerobic work capacity could be maintained with lesser doses of the composition.

Examiner has duly considered Applicant's arguments but deems them moot in light of the new grounds of rejection herein.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (703) 308-1235 and (703) 308-0198, respectively.

FIC
June 30, 2002

JOHN PAK
PRIMARY EXAMINER
GROUP 1600